Application/Control Number: 10/579,014

In The CLAIMS:

 (Currently Amended) A diagnostic device (10, 100, 200, 300) for pathologies of naturally occurring tubular anatomical structures comprising:

a tubular elongated structure (12, 28; 102, 126; 202, 218; 302, 304) developing between a

proximal end and a distal end and being adapted to be inserted in the tubular anatomical structure,

wherein said elongated structure comprises an inner tube and an outer tube adapted to internally

receive said inner tube,

means (22; 138; 230; 308) for locally dilating the walls of the tubular anatomical structure being

associated with the distal end of said elongated structure, said means for locally dilating

comprising a plurality of petals, wherein each petal comprises an arm which can broaden into a

curved surface wherein the curved surface has an asymmetric conformation with respect to the

respective arm, the petals being movable between a closed position, wherein the petals overlap

each other, for the introduction of the device and at least one open position for the viewing and

evaluation of the pathology, and an intermediate position wherein the device is blocked from

being moved to said open position until said handle is further manipulated, said means further

comprising a continuous membrane for engaging dilating tissue in a continuous manner, the

membrane being external to the petals when the petals are overlapping in the closed position,

wherein said means for locally dilating comprise petals being arranged such that one first end

thereof is associated to the distal end of the elongated tubular structure, said petals being adapted

to assume at least one closed configuration and one open configuration,

said inner tube and said outer tube being suitable to translate relatively to each other to open or

close said petals,

control means being associated to the proximal end of the elongated structure, said control means

being operatively connected to said means for locally dilating in order to move them between the

closed position and the open position, and vice versa, said means for locally_dilating having a rounded non-traumatic tip.;

in which said petals are formed as one piece with said outer tube and each of said petals is coupled with a portion of said inner tube forming a unidirectional guide adapted to close or open the petals in response to the translation of the inner tube relative to the outer tube and the petals.

- 2. (Original) The diagnostic device according to claim 1, further comprising means of viewing adapted to be associated with the elongated tubular structure and reach the tract of the tubular anatomical structure dilated by the means of dilating.
- 3. (Original) The diagnostic device according to claim 2, wherein the elongated tubular structure is internally hollow in order to receive the means of viewing.
- 4. (Cancelled) The diagnostic device according to claim 1, wherein said means for locally dilating comprise petals (138; 230; 308) being arranged such that one first end thereof is associated to the distal end of the clongated tubular structure, said petals being adapted to assume at least one closed configuration and one open configuration.
- (Cancelled) The diagnostic device according to claim 4, wherein a petal (138; 230) comprises an arm (140; 232) which broadens into a curved surface (142; 234).
- (Cancelled) The diagnostic device according to claim 5, wherein said curved surface (142; 234)
 has an asymmetric conformation with respect to the respective arm (140; 232).
- 7. (Cancelled) The diagnostic device according to claim 6, wherein said curved surface (142; 234) comprises a side extension (148; 242) suitable to overlap to the adjacent petal at least in the closed configuration of the petals.
- (Currently Amended) The diagnostic device according to the claim -4-1, wherein one of the
 petals a petal (138; 230; 308) comprises at least one detection element or marker (150; 244; 316).
- (Currently Amended) The diagnostic device according to claim -4-1, further comprising a
 membrane (152: 246) being externally arranged on the petals (138: 230: 308).

- 10. (Currently Amended) The diagnostic device according to claim 9, wherein said membrane (152: 246) is made in an elastic material.
- 11. (Currently Amended) The diagnostic device according to claim 9, wherein said membrane (152; 246) is made in a transparent material.
- 12. (Cancelled) The diagnostic device according claim 4, wherein said elongated structure comprises an inner tube (12; 102; 202; 302) and an outer tube (28; 126; 218; 304) adapted to internally receive said inner tube, said inner tube and said outer tube being suitable to traslate relatively to each other to open or close said petals (138; 230; 308).
- (Currently Amended) The diagnostic device according to claim 12_1, wherein an outer surface of the outer tube (28; 126; 218; 304) comprises at least one detection element or marker (33; 128; 220; 306).
- 14. (Cancelled) The diagnostic device according to claim 12, wherein said inner tube (102) has an annular groove (106) adapted to receive and draw an end of said petals (138).
- (Cancelled) The diagnostic device according to claim 14, wherein said outer tube (126) has openings (134) to receive said petals (138).
- 16. (Cancelled) The diagnostic device according to claim 15, wherein at an opening (134) said outer tube (126) comprises a notch (136) suitable to be inserted inside an aperture (146) of a respective petal (138).
- 17. (Cancelled) The diagnostic device according to claim 12, wherein said inner tube (102) has a distal grooved length (206), or a threaded length adapted to receive and draw an end of a petal (230) comprising a toothed area (238).
- (Cancelled) The diagnostic device according to claim 17, wherein said outer tube (218) has openings (226) to receive said petals (230).

- (Cancelled) The diagnostic device according to claim 18, wherein at an aperture (226) said outer tube (218) has presenta seats (228) adapted to receive a pivot (240) of a corresponding petal (230).
- (Cancelled) The diagnostic device according to claim 12, wherein said petals (308) are formed as one piece with said outer tube (304).
- 21. (Cancelled) The diagnostic device according to claim-12, wherein each petal (308) couples with a portion of said inner tube (302) forming a unidirectional guide adapted to close or open the petals subsequent to the translation of the inner tube relative to the outer tube and the petals.
- 22. (Currently Amended) The diagnostic device according to claim 21_1, wherein each petal (308) comprises a longitudinally extending rib (310) and wherein said inner tube comprises a distal flange (312) provided with openings (314) adapted to couple with respective ribs (310) of said petals (308).
- 23. (Currently Amended) The diagnostic device according to claim 22, wherein said rib (310) has a T-shaped cross-section and wherein said openings (314) has a C-shaped cross-section suitable to couple with the cross-section of a respective rib.
- 24. (Currently Amended) The diagnostic device according to one of claim 12 1, wherein said inner tube (12) comprises a holding body (14) arranged at a proximal end of the inner tube and wherein said outer tube (28) comprises a further holding body (34) being arranged at a proximal end of the outer tube.
- 25. (Currently Amended) The diagnostic device according to claim 24, wherein said holding body (14) is made in the shape of a handle.
- 26. (Currently Amended) The diagnostic device according to claim 24, wherein said further holding body (34) comprises a setting ring (42) <u>adapted</u> to define the position of the holding body (14) corresponding to an open configuration of the device.

- 27. (Currently Amended) The diagnostic device according to one claim 24, wherein said further holding body (34) comprises at least one rib (46a, 46b, 46e) adapted to define at least one position of the holding body (14) corresponding to an intermediate open configuration of the device.
- 28. (Currently Amended) The diagnostic device according to claim 12_1, wherein said outer tube (126) comprises a holding body (110) being-arranged at a proximal portion of the <u>outer</u> tube, said holding body (110) comprising a first portion (112) and a second portion (114), suitable to rotate relative to the first portion, and wherein there are further comprised the diagnostic device comprises means for turning which cause a translational movement of the inner tube in response to the rotational movement of the second portion relative to the first portion to a translational movement of the inner tube (102).
- 29. (Currently Amended) The diagnostic device according to claim 12 1, wherein said outer tube (218) comprises a holding body (208) being provided with a trigger (212) adapted to rotate relative to the holding body and wherein there are provided the diagnostic device comprises means for turning which cause a translational movement of the inner tube in response to the rotational movement of the trigger in a translational movement of the inner tube (202).
- 30. (Currently Amended) The diagnostic device according to claim 29, wherein said trigger (212) comprises a toothed area (216) suitable to couple with a proximal grooved length (204), or a threaded length of the inner tube (202).
- 31. (Currently Amended) The diagnostic device according to claim 29, further comprising elastic means (214) being interposed between the holding body (208) and the trigger (212), said elastic means biasing to withdraw the latter trigger in the a resting position.
- 32. (Cancelled) The diagnostic device according to claim 1, wherein said means for dilating comprise arms (22) being arranged such that a first end thereof is associated with the distal end of the elongated tubular structure, said arms being suitable to assume at least one closed configuration and one open configuration.

- 33. (Cancelled) The diagnostic device according to claim 32, wherein at least one arm (22) comprises a straight length (22a) suitable to be fixed to the elongated structure and a curved length (22b).
- 34. (Cancelled) The diagnostic device according to claim 32, wherein at least one arm (22) comprises at least one detection element or marker (25).
- 35. (Cancelled) The diagnostic device according to one of claim 32, further comprising a membrane (26) externally arranged on the arms (22).
- (Cancelled) The diagnostic device according to claim 35, wherein said membrane (26) is made in an elastic material.
- (Cancelled) The diagnostic device according to claim 35, wherein said membrane (26) is made in trasparent material.
- 38. (Cancelled) The diagnostic device according to claim 32, wherein said elongated structure comprises an inner tube (12; 102; 202) and an outer tube (28; 126; 218) adapted to internally receive said inner tube, said inner tube and said outer tube being adapted to traslate relative to each other to open or close said arms (22).
- (Cancelled) The diagnostic device according to claim 38, wherein an outer surface of the outer tube (28; 126; 218) comprises at least one detection element or marker (33; 128; 220).
- 40. (Cancelled) The diagnostic device according to claim 38, wherein an outer surface of the outer tube (12) has grooves (24) adapted to receive at least one portion of an arm (22), respectively.
- 41. (Cancelled) The diagnostic device according to claim 38, wherein said inner tube (12) comprises a holding body (14) arranged at a proximal end of the inner tube and wherein said outer tube (28) comprises a further holding body (34) being arranged at a proximal end of the outer tube.

- 42. (Cancelled) The diagnostic device according to claim 41, wherein said holding body (14) is made in the form of a handle.
- 43. (Cancelled) The diagnostic device according to claim 41, wherein said further holding body (34) comprises a setting ring (42) to define the position of the holding body (14) corresponding to an open configuration of the device.
- 44. (Cancelled) The diagnostic device according to claim 41, wherein said further holding body (34) comprises at least one rib (46a, 46b, 46c) to define at least one position of the holding body (14) corresponding to an intermediate open configuration of the device.
- 45. (Cancelled) The diagnostic device according to claim 38, wherein said outer tube (126) comprises a holding body (110) being arranged at a proximal portion of the outer tube, said holding body (110) comprising a first portion (112) and a second portion (114) adapted to rotate relative to the first portion, and wherein there are further comprised means for turning the rotational movement of the first portion to a translational motion of the inner tube (102).
- 46. (Cancelled) The diagnostic device according to claim 38, wherein said outer tube (218) comprises a holding body (208) provided with a trigger (212) adapted to rotate relative to the holding body and wherein there are provided means to turn the rotational movement of the trigger to a translational movement of the inner tube (202).
- 47. (Cancelled) The diagnostic device according to claim 46, wherein said trigger (212) comprises a toothed area (216) adapted couple with a proximal grooved length (204), or a threaded length of the inner tube (202).
- 48. (Cancelled) The diagnostic device according to claim 46, further comprising clastic means (214) being interposed between the holding body (208) and the trigger (212) to withdraw the latter in the resting position.
- (Cancelled) The diagnostic device according to claim 1, wherein said elongated structure comprises an inner tube (12; 102; 202; 302) and an outer tube (28; 126; 218; 304) adapted to

internally receive said inner tube, said inner tube and said outer tube being adapted to traslate relative to each other in order to open and close said means for locally dilating the walls.

- (Cancelled) The diagnostic device-according to claim 49, wherein the outer surface of the outer tube (28; 126; 218; 304) comprises at least one detection element or marker (33; 128; 220; 306).
- 51. (Cancelled) The diagnostic device according to claim 49, wherein said inner tube (12) comprises a holding body (14) arranged at a proximal end of the inner tube and wherein said outer tube (28) comprises a further holding body (34) being arranged at a proximal end of the outer tube.
- 52. (Cancelled) The diagnostic device according to claim 51, wherein said holding body (14) is made in the form of a handle.
- 53. (Cancelled) The diagnostic device according to claim 51, wherein said further holding body (34) comprises a setting ring (42) in order to define the position of the holding body (14) corresponding to an open configuration of the device.
- 54. (Cancelled) The diagnostic device according to claim 51, wherein said further holding body (34) comprises at least one rib (46a, 46b, 46e) in order to define at least one position of the holding body (14) corresponding to an intermediate open configuration of the device.
- 55. (Cancelled) The diagnostic device according to claim 49, wherein said outer tube (126) comprises a holding body (110) being arranged at a proximal portion of the tube, said holding body (110) comprising a first portion (112) and a second portion (114) adapted to rotate relative to the first portion, and wherein there are further comprised means for turning the rotational movement of the first portion to a translational movement of the inner tube (102).
- 56. (Cancelled) The diagnostic device according to claim 49, wherein said outer tube (218) comprises a holding body (208) being provided with a trigger (212) adapted to rotate relative to

Application/Control Number: 10/579,014

the holding body and wherein there are provided means for turning the rotational movement of the trigger to a translational movement of the inner tube (202).

- 57. (Cancelled) The diagnostic device according to claim 56, wherein said trigger (212) comprises a toothed area (216) suitable to couple with a proximal grooved length (204), or a threaded length, of the inner tube (202).
- 58. (Cancelled) The diagnostic device according to claim 56, further comprising clastic means (214) being interposed between the holding body (208) and the trigger (212) in order to withdraw the latter in the resting position.